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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,390	07/09/2003	Harold N. Trick	KSURF-08151	9787

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EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,390	TRICK ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 26-42* is/are pending in the application.

4a) Of the above claim(s) *7,8,14,21,22,37 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-13,15-20,23,26-36,38-40 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I and invention D in the reply filed on 03/27/06 is acknowledged. Applicant asserts that the election of the invention D is based on species election and that the remaining non-elected inventions will be examined, should the elected invention be found allowable. This is not the case, however, because the restriction requirement between inventions A, B, C, D, and E is not based on election of species. Each of the nematode major sperm protein, RNA polymerase II, Chitin synthase RNA, nematode embryonic lethal phenotype gene, and nematode sterile phenotype gene, constitutes an independent and patentably distinct invention. However, the restriction requirement between A, B, C, D, and E, is subject to the non-allowability of claims 1, 15, 26 and 42. Upon the indication of allowability of claim(s) 1, 15, 26 and 42, the restriction requirement between A-E shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the

claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. The restriction is made FINAL.

Claims 1-23 and 26-42 are pending.

Claims 7-8, 14, 21-22, 37 and 41 are withdrawn from consideration as being directed to a non-elected invention.

Claims 1-6, 9-13, 15-20, 23, 26-36, 38-40, and 42 are under examination.

Claim Objections

At claims 9-12, it is suggested that "seeds", "leaves", "roots", and "stems" be replaced ---seed--, ---leaf---, ---root--, and ---stem---, for clarification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-13, 15-20, 23, 26-36, 38-40, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 6, 15-17, 20, 26, 31-33, 36, 38 and 42 are indefinite in the recitation of "heterologous DNA sequences" which implies two or more DNA sequences. It is

unclear if Applicant intends that more than two DNA sequences can be used and can encode "a double stranded RNA sequence". Clarification is required to more clearly define the metes and bounds of the claims. Dependent claims 4-5, 9-13, 18-19, 23, 27-30, 34-35, and 39-40 are included in the rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. Due to chimerism, not all of the cells from a transgenic plant will comprise in their genome the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed seeds, leaves, roots, and stems, it is unclear whether the claimed seeds/leaves/roots/stems would be distinguishable from seeds/leaves/roots/stems that would occur in nature. See *Diamond v. Chakrabarty* 447 U.S. 303 (1980, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 76 USPQ 280 (1948), and In re Bergy, Coats, and Malik 195 USPQ 344, (CCPA) 1977. Amendment to the claims to recite ---transgenic--- before each "seeds", "leaves", "roots", "stems" would obviate the rejection.

Specification

The disclosure is objected to because of the following informalities: for example, page 34, lines 7 and 26; page 52, line 30; page 53, line 25; page 56, line 8, of the

specification contains an embedded hyperlink directed to an Internet address. The use of hyperlinks and/or other form of browser- executable code are not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser- executable code. See MPEP 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-13, 15-20, 23, 26-36, 38-40, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a transgenic plant comprising heterologous nucleic acid sequences encoding a double stranded nematode RNA sequence that inhibits the proliferation of nematodes ingesting it; said heterologous nucleic acid sequences are at least 21 bases in length and operably linked to the same or separate promoters; a vector comprising said heterologous nucleic acid sequences, and a method for controlling nematodes by growing said transgenic plant expressing said double

stranded RNA, wherein the proliferation of nematodes feeding on said plant is reduced as compared to nematodes feeding on non-transgenic plant tissue. The claims are also drawn to said method, wherein said nematodes are plant or animal parasitic nematodes, and wherein said double stranded is complementary to a nematode embryonic lethal phenotype gene. The claims are further drawn to said method/vector/transgenic plant, wherein the promoter is tissue specific or constitutive. In contrast, Applicant describes the plant parasitic nematode sequences for H. glycines major sperm protein, RNA polymerase II, and chitin synthase and their use to transform plants by dsRNA to inhibit nematode infection in the plant. These are genus claims.

In *Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), the court stated:

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention... Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself (43 USPQ2d at 1404).

The court held that held that human insulin-encoding cDNA is not described by prophetic example, which sets forth only a general method for obtaining the human cDNA:

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity...Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes...does not necessarily describe the DNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA....Accordingly, the specification does not provide a written description of human cDNA (43 USPQ2d at 1405).

The description of a single species of rat cDNA was held insufficient to describe the broad genera of vertebrate or mammalian insulin:

"In claims to genetic material...a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written

description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It doesn't define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function...does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is (43 USPQ2d at 1406).

The court continued:

"Thus...a cDNA is not defined by the mere name 'cDNA', even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA...A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus". (43 USPQ2d at 1406). See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The nucleic acids of the claims are described by function only.

In *Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), the court stated:

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties", ... Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself (43 USPQ2d at 1404). See also, the MPEP 2163 which states "One must define a compound by "whatever characteristics sufficiently distinguish it". See also in re Koller, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) which requires that "original claims constitute their own description".

Applicant has not described genes from non-plant parasitic nematodes capable of inducing dsRNA and having nematocidal activity upon expression in a transgenic plant. Applicant has not described how to identify plant parasitic and non-parasitic nematodes that are suitable for the production of the claimed nematode resistant transgenic plants. Applicant has not described the composition and structure of a "nematode embryonic lethal phenotype gene"; such gene is not known in the prior art.

The state of the prior art as evidenced by Hussey et al (Braz. J. Plant Physiol., 14(3): 183-194 (2002) is that a large number of plant nematode parasitism candidate genes encoding novel proteins are identified; however, over 70% of the parasitism genes have no homology with functionally annotated genes in the databases. Hussey et al suggest that the characterization of the target plant parasitism genes is essential before one desires to develop nematode resistant transgenic plants including expression of dsRNA that specifically inhibit target nematode parasitism genes.

Applicant has not described a representative number of nucleic acids encoding dsRNA nematode sequences having nematocidal activity for the production of nematode resistant transgenic plants. A review of the literature does not indicate that the nucleic acids are well known or can be easily identified. Consequently, the claimed transgenic plant, seed/leaves/stem, vectors and methods for controlling nematode are not adequately described.

See also, the *University of Rochester v. G.D. Searle* & Co., Inc.(, U.S. District Court, Western District of New York, Decision and Order No. 00-CV-6161L,) decided 05 March 2003, at page 8, bottom paragraph, that method claims are properly subjected to

a written description requirement if the starting material which requires that method is itself inadequately described. The court specifically stated, "(T)he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment. It means little to "invent" a method if one does not have possession of a substance that is essential to practicing that method. Without that substance, the claimed invention is more theoretical than real;..... and there is no meaningful possession of the method."

Therefore, the claimed invention does not meet the current written description requirements. See, also, the Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6, 9-13, 15-16, 18-20, 23, 26-27, 29-35, 38-40, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Tobias et al (WO 01/37654).

The claims are drawn to a transgenic plant comprising heterologous nucleic acid

sequences encoding a double stranded nematode RNA sequence that inhibits the proliferation of nematodes ingesting it; said heterologous nucleic acid sequences are at least 21 bases in length and operably linked to the same or separate promoters; a vector comprising said heterologous nucleic acid sequences, and a method for controlling nematodes by growing said transgenic plant expressing said double stranded RNA, wherein the proliferation of nematodes feeding on said plant is reduced as compared to nematodes feeding on non-transgenic plant tissue. The claims are also drawn to said method, wherein said nematodes are plant or animal parasitic nematodes, and wherein said double stranded is complementary to a nematode embryonic lethal phenotype gene. The claims are further drawn to said method, vector, and transgenic plant, wherein the promoter is a tissue specific or constitutive promoter.

Tobias et al teach methods of inhibition of parasitic nematodes in a plant by transforming the plant with DNA sequences encoding a dsRNA that targets substantially identical endogenous genes or gene portions; said endogenous genes are essential in nematode development and reproduction; the dsRNA may be at least 25 nucleotides in length and is expressed in feeding cells which is taken up by the parasitic nematode via its stylet. The cited reference also teaches production of dsRNA in the transgenic plant or root cultures, and analysis of the transgenic plants for resistance against *M. incognito*. The cited reference further teaches generation of plant expression vectors comprising tissue-specific or constitutive promoters for expression of one or both DNA sequences and transformed plants and plant cells expressing dsRNA and having nematocidal activity as compared to a non-transformed plant. Tobias et al specifically

teaches transgenic plants expressing a dsRNA for M. incognita unc-17 encoding vesicular acetylcholine transporter; if this gene is absent or mutated, proper development of the nematode is stopped. Claims 13 and 39 are included in the rejection because no structural characteristics that would distinguish "a nematode embryonic lethal phenotype gene" from the prior art DNA sequence are recited in the claims or provided in the specification (see at least pages 17-18; 20-22; 28-29; 36-39; and claims on pages 40-43).

Claims 1-5, 13, 15-20, 23, 26-36, 38-40, and 42 are rejected under 35 U.S.C. 102(a) as being anticipated by MUSHEGIAN et al (WO 01/96584).

MUSHEGIAN et al teach a method of inhibiting nematodes in a plant by transforming the plant with polynucleotide sequences encoding a double stranded RNA or RNAi molecules; the sense and antisense polynucleotide sequences are separated by a linker sequence; the dsRNA comprises a sequence identical to a target gene (or fragment thereof) linked directly or indirectly, to a polynucleotide sequence complementary to the sequence of the target gene (or fragment thereof). The target genes for disruption in the nematode include genes encoding proteins involved in ribosome assembly, transport proteins, protein production, folding and processing, production of polynucleotides; the dsRNA is expressed in plant cells including root cells that is taken up by nematodes during feeding to block the function of the target gene (see at least pages 6-7). MUSHEGIAN et al also teach plant expression vectors comprising polynucleotide sequences encoding double stranded RNA or RNAi

molecules operably linked to a root-specific promoter or constitutive nematode inducible promoter and transgenic plant and plant tissue expressing said vectors (see at least pages 27-30; Fig. 8, and claim 141). Therefore, MUSHEGIAN et al teach all claim limitations.

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0795.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/5/06
Mai

MEDINA A. IBRAHIM
PRIMARY EXAMINER